

## Message Text

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ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-07 OPR-02 /028 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB  
APPROVED BY OES/ENP/EN: WJWALSH, III  
DHEW/PHS/OASH/OIH: REVANS  
EA/J:BBROWN(INFO)

-----067650 210455Z /15

P 202242Z MAR 78  
FM SECSTATE WASHDC  
TO AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 071555

E.O. 11652: N/A

TAGS: OTRA, OCON, TBIO, JA

SUBJECT: VISIT OF FDA REPRESENTATIVES - APRIL 1978

REFERENCES: TOKYO 0029; STATE 296029

1. FDA APPRECIATES ASSISTANCE OF EMBASSY IN ARRANGING FOR REPRESENTATIVES TO MEET APPROPRIATE MEMBER OF JAPANESE PHARMACEUTICALS AFFAIRS BUREAU (PAB) IN TOKYO APRIL 10-12, 1978.

2. MR. HALPERIN, ACTING DEPUTY DIRECTOR, BUREAU OF DRUGS, ACCOMPANIED BY HIS WIFE, WILL DEPART WASHINGTON, DC ON THURSDAY APRIL 4, 1978 AT 7:10 AM ARRIVING IN TOKYO ON APRIL 5 AT 5:20 PM ON PANAM FLIGHT NO. 801. THEY HAVE RESERVATIONS AT THE HOTEL NEW OTANI.

3. MR. BYERS, ASSOCIATE DIRECTOR FOR COMPLIANCE, BUREAU OF DRUGS, WILL DEPART WASHINGTON, DC ON APRIL 8, 1978 AT 9:45 AM ARRIVING IN TOKYO APRIL 9 AT 4:00 PM ON NORTHWEST  
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ORIENT FLIGHT NO. 3. HE HAS RESERVATIONS AT THE HOTEL OKURA.

4. FDA REPRESENTATIVE PROPOSE TO MEET WITH SCIENCE COUNSELOR ON MONDAY MORNING, APRIL 10. PROPOSED AGENDA

FOR US FDA-JAPANESE PAB MEETING HAS BEEN AIRMAILED TO

EMBASSY MARCH 8, 1978.

5. FOLLOWING MEETING, FDA REPRESENTATIVES WOULD, IF FEASIBLE, LIKE TO VISIT PHARMACEUTICAL FIRM, TOKYO AND MR. BYERS WOULD LIKE TO VISIT PHARMACEUTICAL INSTALLATION IN OSAKA.

6. FDA REPRESENTATIVES WILL ALSO BE AVAILABLE TO MEET WITH SENIOR TECHNICAL STAFFS OF U.S. DRUG MANUFACTURERS IN JAPAN, IF EMBASSY FEELS THIS IS APPROPRIATE AND DESIRABLE.

7. MR. BYERS PLANS TO RETURN TO THE U.S. ON APRIL 15 ON NORTHWEST ORIENT FLIGHT NO. 8 AND MR. HALPERIN AND WIFE PLAN TO RETURN TO THE U.S. APRIL 18 ON NORTHWEST ORIENT FLIGHT NO. 4.

8. FDA REPS WILL REQUIRE SERVICES OF AN INTERPRETER FOR MEETINGS ON APRIL 10, 11 AND 12. CAN EMBASSY ARRANGE FOR SAME? FDA WILL PAY IF NECESSARY. PLEASE CABLE WHAT ARRANGEMENTS ARE POSSIBLE AND COST.

9. ANY ADDITIONAL ASSISTANCE EMBASSY CAN PROVIDE IN FACILITATING VISIT OF FDA REPRESENTATIVES WILL BE APPRECIATED. PLEASE ADVISE IF YOU WISH TO MAKE SOME SUGGESTIONS CONCERNING AGENDA OR OTHER ARRANGEMENTS. VANCE  
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## Message Attributes

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